April 16, 2012

Ms. Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6037-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Reporting and Returning of Overpayments

Dear Acting Administrator Tavenner,

The undersigned surgical and anesthesia organizations appreciate the opportunity to provide comments in response to the proposed rule: *Medicare Program; Reporting and Returning of Overpayments* (Proposed Rule) that was published in the *Federal Register* on February 16, 2012. We appreciate the Centers for Medicare & Medicaid Services' (CMS) efforts to provide more clarity with respect to section 6402(a) of the Patient Protection and Affordable Care Act (ACA); however, we have serious concerns with several provisions of this Proposed Rule, and we also point out areas of ambiguity that could lead to further confusion if the Proposed Rule is finalized as currently articulated. Our comments are presented in the order in which issues of interest appear in the Proposed Rule.

Background

The Proposed Rule implements section 6402(a) of the ACA, which requires that an overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained after this deadline constitutes an "obligation" for purposes of the federal civil False Claims Act (FCA), and providers could also be subjected to possible Medicare and Medicaid exclusion and civil monetary penalties under the federal Civil Monetary Penalty (CMP) statute.

Provisions of the Proposed Regulation

Definitions

CMS proposes to use the same definition of "overpayment" as used in section 6402(a) of the ACA, namely "any funds that a person receives or retains under title XVII . . . to which the person, after applicable reconciliation, is not entitled under such title."[1] CMS

[1] Proposed 42 C.F.R. § 401.303.

should make clear in the final rule that potential overpayments only exist if a provider retains funds to which the provider was not entitled *at the time that the person received the funds*. Subsequent changes in laws, regulations, or other applicable guidance should not make a provider's receipt of funds be considered an overpayment for the purposes of the Proposed Rule if the receipt of funds would not have otherwise been considered an overpayment at the time the provider received those funds.

In addition, CMS should consider a minimum threshold overpayment amount to trigger liability under this policy. There are circumstances under which providers have been overpaid by extremely small amounts. It would be inequitable to expose providers to CMP liability and possible exclusion from participation in federal health care programs in such cases. CMS could possibly explore alternative methods that are separate from the requirements of section 6402(a) of the ACA for providers to report small overpayments.

Requirements for Reporting and Returning Overpayments

1. General

CMS proposes to implement the reporting and returning of overpayments requirement by using the existing voluntary refund process, which will be renamed the "self-reported overpayment refund process." Under this process, providers report overpayments using a form that each Medicare contractor makes available on its Web site. The Proposed Rule also requires providers to summarize why the refund is being made in a report that details 13 required pieces of information. Two of these elements include health insurance claims numbers and Medicare claim control numbers; however, those numbers may not be readily available, especially if the overpayment is identified based on statistical sampling. **We urge CMS to create an exception for the claim number requirement in cases where overpayments were identified based on statistical sampling.**

Although the Proposed Rule directs providers to report overpayments using the form made available by its Medicare contractor, some existing forms do not incorporate all 13 of the mandated elements for a report. For example, the Cahaba GBA[2] and Palmetto[3] overpayment refund forms do not include one or more of the elements required by the Proposed Rule. **We request that CMS clarify that until the Agency creates a uniform reporting form, a provider is only required to provide the information requested in its Medicare contractor's overpayment refund form.**

2. "Identified" and Reporting and Returning Deadlines

According to the Proposed Rule, a person has "identified" an overpayment if a person has "*actual knowledge of the existence of the overpayment or acts in reckless disregard or*

[2] *See*, Cahaba GBA, Overpayment Refund/Notification Form, *available at* https://www.cahabagba.com/part_b/forms/overpayment_refund.pdf (last accessed Apr. 5, 2012).
[3] *See*, Palmetto GBA Medicare, J1 Overpayment Refund Form, *available at* http://www.palmettogba.com/Palmetto/Providers.Nsf/files/J1_overpayment_refund_form_revised.pdf/$File/J1_overpayment_refund_form_revised.pdf (last accessed Apr. 5, 2012).

deliberate ignorance of the existence of the overpayment."[4] CMS believes that the ACA's provision that the term "knowing" have the same meaning as "knowing" for purposes of the federal FCA[5] indicates Congress' intent to apply the FCA's knowledge standard to "identified" as well for the purposes of the Proposed Rule. CMS also proposes that the 60-day requirement to report and return overpayments would run from the date on which the provider had identified the overpayments. In addition, CMS proposes that if a provider receives information concerning a potential overpayment, that receipt of information could create an obligation to make a "reasonable inquiry" with "all deliberate speed" to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, then the provider has 60 days to report and return the overpayment

There is no statutory basis to apply the expansive FCA knowledge standard to the definition of "identified" for the purposes of the Proposed Rule. We do not agree that simply because the ACA defines "knowing" as having the FCA definition of that term, that it was also Congress' intent to apply the same FCA knowledge standard to "identified" as used in section 6402(a) of the ACA as well. Moreover, a previous version of the ACA, H.R. 3962, used the FCA knowledge standard for the section on reporting and returning of overpayments, but the use of the FCA knowledge standard was specifically rejected in the final version of the ACA, which replaced the word "knows" with "identified."[6] This is indicative of Congressional intent *not* to equate the FCA knowledge standard to "identified" as used in section 6402(a) of the ACA. In addition, the obligation to make a "reasonable inquiry" "with all deliberate speed" appears to set an even higher standard than the FCA. **Therefore, we urge CMS to define these terms less broadly in order to implement the regulation congruent with Congressional intent and to assure that providers' limited resources to investigate overpayments are utilized appropriately.**

The Proposed Rule also lists several examples of when an overpayment is "identified" for the purposes of this policy, two of which include:

- A provider receives an anonymous compliance hotline complaint about a potential overpayment and fails to make a reasonable inquiry into the complaint; and
- A provider is informed by a government agency of an audit that discovered a potential overpayment, and the provider fails to make a reasonable inquiry.

The anonymous compliance hotline complaint example highlights our concern that the Proposed Rule does not set a floor for how strong the evidence of a potential overpayment should be in order to trigger a provider's obligation to make a reasonable

[4] Proposed 42 C.F.R. § 401.305(a)(2).

[5] The FCA definition of "knowing" means that a person, with respect to information, (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (ii) acts in reckless disregard of the truth or falsity of the information. This definition requires no proof of specific intent to defraud. *See* 31 U.S.C. 3729(b)(1).

[6] H.R. 3962 states that a person must report and return an overpayment if the person "knows" of the overpayment. This section also defines "knows" as having the meaning given in "knows" and "knowledge" of section 3729(b) of title 31 of the United States Code (the FCA). *See* H.R. 3962, 111th Cong., § 1641 (2009).

inquiry. Because the consequences of failing to make a reasonable inquiry with all deliberate speed are so harsh (i.e. potential FCA, CMP, and exclusion liability), providers could feel pressure to rapidly investigate even the most remote and far-fetched indication that an overpayment might have occurred. **Accordingly, we urge CMS to specify that providers are to further investigate *credible* information concerning a potential overpayment.**

Regarding the example above where a provider is informed by a government agency of an audit that discovered a potential overpayment, **we request that CMS clarify that notification by a government agency be *specific* to a provider in order to trigger the requirement for a reasonable inquiry into the potential overpayment.** We do not believe that general government agency notices to all providers or to a large organization should prompt an overpayment inquiry by all providers or all providers in that organization.

In addition, the above examples and the others set forth in the Proposed Rule for when an overpayment is "identified" do not distinguish between the discovery of the *existence* of an overpayment and the ability of a provider to *quantify* the amount of the overpayment. It is unclear whether the 60-day clock would start once the existence of an overpayment has been determined, even if the amount is not yet quantified or whether an overpayment must first be quantified in order to be considered "identified." It is also unclear what action a provider should take if it knows it has been overpaid, but cannot quantify the overpayment within 60 days (even after a reasonable inquiry has been conducted with all deliberate speed) or how CMS would handle an investigation that extends beyond 60 days. **CMS should provide additional guidance on whether a provider's ability to quantify an overpayment affects the determination of whether an overpayment has been identified.**

CMS states in the Proposed Rule that it recognizes intersections between the obligations to report and return overpayments under section 6402(a) of the ACA and the existing procedures for providers to self-disclose actual or potential violations of the physician self-referral statute to CMS though the Medicare Self-Referral Disclosure Protocol (SRDP). As a result, CMS proposes to suspend the obligation to *return* overpayments required under the Proposed Rule when CMS acknowledges receipt of a disclosure made pursuant to the SRDP. Likewise, CMS proposes to suspend the obligation to *return* overpayments required under the Proposed Rule when the OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol (SDP), which enables providers to self-disclose evidence of potential fraud to the OIG. CMS indicates that a disclosure under the SDP satisfies the reporting requirement under the Proposed Rule, but a disclosure under the SRDP does not satisfy the Proposed Rule reporting requirement**. In order to avoid duplicate reporting, we encourage CMS to consider a report made under the SRDP to also constitute a report for the purposes of the Proposed Rule.** We are aware of no policy basis for differential treatment of the SRDP and the OIG SDP.

3. Applicable Reconciliation

The Proposed Rule describes applicable reconciliation as restricted to cost report reconciliation. Although the Proposed Rule addresses cost report reconciliation, it is silent with respect to existing claims appeals processes. Providers currently use existing claims correction processes to resolve overpayments that are identified within one year. **We request guidance from CMS as to how the Proposed Rule affects the availability of Medicare's existing claims appeals processes. We urge CMS to refrain from discontinuing useful and workable claims appeals processes on which providers rely.**

In addition, there could be circumstances in which a provider receives notice of an overpayment via existing CMS auditors such as Recovery Audit Contractor (RACs). CMS should clarify how the appeals processes of these and other types of CMS audit programs affect the Proposed Rule. **We urge CMS to work toward alignment of the Proposed Rule with existing CMS auditors' appeals processes by suspending the reporting and repayment requirements under the Proposed Rule if a provider is notified of an overpayment via a CMS overpayment initiative (such as a RAC), and files an appeal via that auditor's existing appeals process.** If a provider has appealed an overpayment in these circumstances we believe that an overpayment would not yet qualify as "identified" and the 60-day clock should not start until a decision has been reached with respect to the RAC appeal.

4. Lookback Period and Related Issues

CMS proposes that overpayments must be reported and returned if a person identifies the overpayment within 10 years of the date the overpayment was received. CMS selected this time frame because the FCA statute of limitations is between six and 10 years, and CMS chose the outer limit of this statute of limitations. CMS also proposes to amend the reopening rules to provide that overpayments may be reopened for a period of 10 years.

We are strongly opposed to these proposals, and we urge CMS to refrain from implementing the proposed 10-year lookback period and the amendment allowing claims to be reopened for a period of 10 years. There is no clear statutory basis for the 10-year lookback period. The six to 10-year FCA statute of limitations was intended to address intentional fraud, and this proposal inappropriately links routine payment errors to the FCA liability standard. Also, CMS should provide more information on how the proposed 10-year lookback period affects Medicare's "without fault" rules, which deem claims to be final after four years.[7] In addition, it is unclear in the case of a FCA settlement for a billing issue going back six years whether a provider would then be liable for the remainder of the 10-year lookback period.

[7] *See, e.g.*, 42 C.F.R.§ 405.350(c) (a provider of services, in the absence of evidence to the contrary, may be deemed to be without fault if CMS or its contractor determines the payment amount was incorrect subsequent to the third year following the year in which the provider was paid).

This policy also fails to recognize the varying levels of difficulty in investigating inadvertent payment errors compared with intentional fraud. In the cases contemplated under this regulation, assuming the medical records have been retained, such an investigation would also include how laws, regulations, and any other applicable guidance have changed over the 10 years. In the case of intentional fraud this is difficult, but it is more complicated with respect to simple payment errors. This policy also places an additional burden on providers who close their practices or retire. It would be extremely difficult for such providers to comply with these requirements going back 10 years.

It is also unclear from the Proposed Rule whether liability exists for overpayments identified prior to March 23, 2010. Given the significant burden and complexity of determining some overpayments and overpayment amounts, in addition uncertainty regarding the legality of retroactive application of this policy, **we urge CMS to clarify in the final rule that the reporting and returning of overpayments requirements do not apply to overpayments identified prior to March 23, 2010**.

Not only does the 10-year lookback period raise significant concerns, but the existing Medicare claims reopening regulations adequately address reopening issues in order to implement section 6402(a) of the ACA. Currently the Medicare reopening regulations allow for a claim to be reopened within four years for good cause and there is no express limit for reopening where there is evidence of fraud.

Finally, the Proposed Rule only extends the reopening rules as they relate to *overpayments*. It is inequitable for CMS to impose a 10-year lookback period for identifying overpayments without also allowing the same lookback period for identifying underpayments.

We urge CMS not to implement the proposed 10-year lookback period and the amendment allowing claims to be reopened for a period of 10 years, and we request that CMS provide additional guidance in response to the issues raised above.

Regulatory Impact Statement

CMS estimates that approximately 8.5 percent of the total number of Medicare providers will report and return overpayments in a typical year under the Proposed Rule, and that each of these providers would report and return approximately three to five overpayments. CMS also estimates that it would take a provider approximately 2.5 hours per overpayment to complete the applicable reporting form and return the overpayment and that the average hourly wage of individuals involved with completing and submitting applicable reporting forms (accountants and administrative personnel) will be $37.10 per hour.

We disagree with these estimates, which seem far too low. **We believe CMS is underestimating both the complexity involved with investigating and calculating an overpayment and the number of improperly paid claims per year. In addition,**

CMS' cost estimate only considers the salaries of accountants and administrative personnel, but does not include attorneys or billing consultants, who may also be involved. Thus, we urge CMS to recalculate the regulatory impact statement to reflect these realities.

We appreciate the opportunity to offer these comments regarding the Reporting and Returning of Overpayments proposed rule. If you have any questions about our comments, please contact Bob Jasak in the American College of Surgeons' Division of Advocacy and Health Policy. He can be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American Association of Hip & Knee Surgeons
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Osteopathic Surgeons
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Osteopathic Academy of Orthopedics
American Society of Anesthesiologists
American Society of Breast Surgeons
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society of General Surgeons
American Society for Metabolic and Bariatric Surgery
American Society of Plastic Surgeons
American Society of Surgery for the Hand
American Urological Association
Cervical Spine Research Society
Congress of Neurological Surgeons
Maryland Orthopaedic Association
Orthopedic Rehabilitation Association
Orthopedic Trauma Association
Pediatric Orthopedic Society of North America
Scoliosis Research Society
Society for Vascular Surgery
The American Orthopedic Foot & Ankle Society
The Eastern Orthopaedic Association
The Hip Society
The Knee Society
Western Orthopaedic Association